

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 EB-07 COME-00 MED-03 /033 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

ARA/EX:KDACKERMAN(INFO)

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P 082321Z APR 76

FM SECSTATE WASHDC

TO AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY PANAMA PRIORITY

AMEMBASSY CARACAS PRIORITY

AMCONSUL RIO DE JANEIRO PRIORITY

INFO AMEMBASSY BRASILIA PRIORITY

UNCLAS STATE 085281

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BR, GT, PN, VE

SUBJECT: FDA ADVISORY - RECALL OF IN VITRO DIAGNOSTIC
KITS DUE TO CHEMICAL DECOMPOSITION OF REAGENTS
(RECALL NUMBERS T-075-6 THROUGH T-081-6)

1. FDA ADVISES THAT THE FOLLOWING ARE BEING RECALLED:

PRODUCTS INVOLVED/LOT NUMBERS:

A. T-075-6 HYCEL NO. 198B PHOSPHOROUS REAGENT SET -
PHOSPHOROUS SURFACTANT - FOR IN VITRO DIAGNOSTIC USE,
LOT NOS. 4015A1, 4045A1, 4116A1, 4195A1, 4275A1.

B. T-076-6 HYCEL NO. 198BMX PHOSPHOROUS REAGENT SET -
PHOSPHOROUS SURFACTANT - FOR IN VITRO DIAGNOSTIC USE,
LOT NOS. 4032A1, 4104A1, 4154A1, 4196A1, 4273A1.

C. T-077-6 HYCEL NO. 235 ACID PHOSPHATASE TEST SET -
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ACID PHOSPHATASE SUBSTRATE - COLOR REAGENT SET -

PHOSPHATASE STANDARD FOR IN VITRO DIAGNOSTIC USE,
LOT NO. 4141A1.

D. T-078-6 HYCEL NO. 237B ACID PHOSPHATASE COLOR REAGENT
SET FOR IN VITRO DIAGNOSTIC USE, LOT NO. 4033A1.

E. T-079-6 HYCEL NO. 900 CPK PHOSPHOROUS REAGENT TEST
KIT FOR IN VITRO DIAGNOSTIC USE, LOT NO. 4181A1.

F. T-080-6 HYCEL NO. 903B CPK PHOSPHOROUS REAGENT TEST
KIT FOR IN VITRO DIAGNOSTIC USE, LOT NOS. 4046A1,
4274A1.

G. T-081-6 HYCEL NO. 903BMX CPK PHOSPHOROUS REAGENT
TEST KIT FOR IN VITRO DIAGNOSTIC USE, LOT NO. 4035A1.

MANUFACTURER/RECALLING FIRM:

HYCEL INC.
7920 WEST PARK DRIVE
HOUSTON, TEXAS 77024

REASON FOR RECALL:

STABILITY PROBLEMS WERE DETERMINED IN TWO COMPONENTS,
NAMELY, "PHOSPHORUS REAGENT" AND "PHOSPHORUS SURFACTANT",
WHICH ARE COMPONENTS OF THE PREVIOUSLY DESCRIBED "SETS".
THESE PHOSPHORUS REAGENTS WERE PREVIOUSLY MANUFACTURED
AS A ONE COMPONENT REAGENT (REAGENT PLUS SURFACTANT)
WITH AN EXPIRATION DATE OF 5 MONTHS. FOR ECONOMIC
REASONS, THE FIRM CONDUCTED ACCELERATED STABILITY
STUDIES DURING 1975. THESE STABILITY STUDIES WERE
CONDUCTED BY SEPARATING THE REAGENT AND SURFACTANT INTO
2 SEPARATE COMPONENTS. THESE ACCELERATED STUDIES
REPORTEDLY SHOWED A ONE YEAR EXPIRATION DATE COULD BE
USED WHEN THE PHOSPHORUS REAGENTS WERE PACKAGED AS 2
SEPARATE COMPONENTS. MANUFACTURING OF THE 2-PART
PHOSPHORUS REAGENTS BEGAN IN SEPTEMBER AND OCTOBER
1975. ON NOVEMBER 1, 1975, THE FIRM BEGAN DISTRIBUTING
THE PHOSPHORUS REAGENTS AS TWO SEPARATE COMPONENTS WITH
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AN EXPIRATION DATE OF ONE YEAR. FOLLOWING RECEIPT OF
CONSIGNEE COMPLAINTS DEALING WITH FALSE READINGS, THE
FIRM'S QUALITY CONTROL DEPARTMENT RAN ANALYTICAL
ASSAYS, THE RESULTS OF WHICH SHOWED THE PHOSPHORUS
REAGENTS COMMON TO ALL RECALLED PRODUCTS, DECOMPOSE OR
BECOME UNSUITABLE IN ASSAY AFTER ONE MONTH FROM THE
DATE OF MANUFACTURE. AS A RESULT, ON JANUARY 20, 1976
THE FIRM SENT RECALL NOTICES TO ALL INTERNATIONAL

DISTRIBUTORS VIA TELEX AND/OR LETTERS REQUESTING
RECALL AND DESTRUCTION OF ALL RECALLED SETS.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED RECALL TELEX AND/OR
LETTER FROM FIRM. ANY QUESTIONS CONSIGNEES MAY HAVE
REGARDING THIS RECALL SHOULD BE DIRECTED TO FIRM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

INSTRUCTOMATIC DO BRAZIL
RIO DE JANIERO
BRAZIL

LABORATORIES CLINICOS
GUATEMALA CITY
GUATEMALA

DR. ENRIQUE HERRARTA
GUATAMALA CITY
GUATEMALA

PROMED
APARTADO 6281
PANAMA 5
PANAMA

AMERICAN HOSPITAL SUPPLY CORP.
CARACAS 5
VENEZUELA SISCO

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Message Attributes

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Disposition Approved on Date:
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Margaret P. Grafeld
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TAGS: OGEN, ETRD, TBIO, BR, GT, PN, VE, FDA
To: GUATEMALA
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